Alwood, Jim

From: Alwood, Jim
Sent: Wednesday, October 25, 2017 2:37 PM
To: 'James Ede'
Subject: RE: EPA Nano Rule

James – I have been considering your questions. They are difficult to answer in the abstract and because "nanomaterials" encompasses a wide variety of chemicals I am not sure my answers will be very helpful generally. There just isn't a one size fits all for nanomaterials. If you are working with a client with a specific question about a nanomaterial EPA will always be happy to provide some input on the question or determination the client is asking about.

Jim

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From: James Ede [mailto:jede@vireoadvisors.com]
Sent: Tuesday, October 24, 2017 6:03 PM
To: Alwood, Jim <Alwood.Jim@epa.gov>
Subject: Re: EPA Nano Rule

Greetings Jim Alwood,

Curious if you have had a chance to review the questions below regarding the EPA's Section 8(a) Information Gathering Rule on Nanomaterials in Commerce (originally sent October 20th). I understand you're likely busy, so alternatively - if you could provide contact information for someone else who may be able to answer my questions - I can reach out to them.

Thanks for your time,
James

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> On Oct 20, 2017, at 11:23 AM, James Ede <jede@vireoadvisors.com> wrote:
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> Greetings Jim Alwood,

I have a few question regarding EPA's Section 8(a) Information Gathering Rule on Nanomaterials in Commerce and hope you can provide some guidance or clarification.

One of the criteria for a reportable chemical substance is 'more than 1% of any particles, including aggregates and agglomerates, *measured by weight* are in the size range of 1-100nm in at least one dimension. Although only 'readily ascertainable' information needs to be used in making a determination if a company must report (i.e. no testing is required), several clients have had questions about how they can determine if their materials meet this requirement and want to be proactive.

Q1. Does the EPA have any methods, or recommended standards for completing particle size distributions by weight or calculating particle size distributions by weight? We are accustom, and only have protocols for, completing particle size distributions for nanomaterials by number.

A1. EPA does not have any specific recommendations or standards for determining/calculating particle size distribution by weight. There are numerous acceptable methods and their applicability with vary depending on the nanomaterial and the physical form. If a company has a specific question about applicability of a method for a specific nanomaterial its possible EPA could give a reason why that method may not work for that nanomaterial. Because the rule does not require testing EPA will be reluctant to suggest specific methods.

Another criteria for a reportable chemical substances is 'unique and novel properties'. The guidance does a good job of explaining that enhanced, or continuously scaling properties (e.g. surface area) are not considered unique and novel. My understanding is this also requires intent - the unique and novel property must be the reason the material is manufactured at the nanoscale. However, the answer to Q5 in your working guidance confuses my understanding:

"Surface area is not considered a unique and novel property. It will vary proportionately with a smaller particle size. However, if another intrinsic property changes as a result of the smaller particle size/increased surface area, and if that other property is the reason that the substance is manufactured at that particle size range, than that other intrinsic property would be considered a unique and novel property and the material would be reportable."

Many substances are manufactured at the nanoscale primarily for increased surface area (which is not considered unique and novel), but this is primarily done for the technical benefits it conveys. For example, using a nanomaterial in a formulation (with it's increased surface area) may result in reduced metal loading of another ingredient (e.g. metals). Or, as might be the case in food contact materials, the increased surface area of a nanomaterial might effectively 'bind' a formulation together, and prevent migration to food stuff.

Q2. How do we navigate the EPA Nano Rule to determine if 'technical benefits' from having increased surface area might be considered 'unique and novel'? In the examples above, reduced metal loading in a formulation is nano-specific (will not happen with bulk material) but is due entirely to the increased surface area of the substance (which is not considered unique and novel).

A2. The best answer I can give here is to focus on the intrinsic properties of the chemical. If the nano material has the same basic properties and function as the non-nano form (what you are calling the bulk material), then any properties that are enhanced (more reactive) or physical

(smaller particles disperse better than larger ones) are not considered unique and novel. If however those "technical benefits" are because the chemical now has different properties or functions then they would be considered unique and novel. One of the examples in the guidance is that the chemical changed from a blue color to a red color. If in your example a company is not exactly sure what those technical benefits are and they only know it works better at the nanoscale, it will make the determination of a unique/novel property less clear. To answer Q3 you can always consult with EPA for help in making a determination for a specific chemical before reporting.

Q3. If we still have questions about whether a client meets the 'unique and novel properties' requirement, is there a way we can consult with the EPA to make this determination before reporting?

I appreciate any clarification you can provide.

Kind regards,

James

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